K092877

5. 510(k) Summary

NOV 17 2009

Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

C. Company Phone: (905) 602-4875; ext 252

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: 09-Nov-2009

Device Identification

A. Device Trade Name: InDiscal™ Aspiration Kit

The InDiscal™ Aspiration Kit includes the InDiscal™ Aspiration Device, InDiscal™ Aspiration Introducer, InDiscal™ Aspiration Plug, InDiscal™ Aspiration Kit, InDiscal™ Aspiration Cap, InDiscal™ Aspiration Sheath

B. Device Common Name: Percutaneous Discectomy Probe

C. Classification Name: Arthroscope and Accessories, 21 CFR 888.1100

D. Device Class: Class II

E. Device Code: HRX

Identification of Predicate Device

Device name	Manufactured by	510(k) number
Nucleotome Probe (L Kit)	Surgical Dynamics	K942987
Nucleotome Probe (E Kit)	Surgical Dynamics	K931109
Nucleotome 3.5 mm Automated Percutaneous Lumbar Probe	Surgical Dynamics	K923525
Nucleotome® II (Version2) Tissue Aspirator/Cutter	Surgical Dynamics	K914282
Surgical Dynamics Nucleotome II Tissue Aspirator/cutter	Surgical Dynamics	K902778
21200 Nucleotome Probe Set	Surgical Dynamics	K040919

Device Description

The InDiscal™ Aspiration Device is a sterile, single-use device that is inserted through the InDiscal™ Aspiration Introducer into the patient to aspirate tissue disc material. The device consists of a handle, coring needle with sheath, storage chamber and activation switch.

The InDiscal™ Aspiration accessories include the InDiscal™ Aspiration Introducer, InDiscal™ Aspiration Plug, InDiscal™ Aspiration Cap, InDiscal™ Aspiration Sheath

Intended Use

The InDiscal Aspiration Device and Accessories are intended for aspiration of disc material during percutaneous discectomies in the lumbar, thoracic, and cervical regions of the spine.

Substantial Equivalence

The intended use of the InDiscal™ Aspiration Device and accessories is substantially equivalent to the Nucleotome probe predicate devices. The method used to remove the tissue for InDiscal™ Aspiration Device and Nucleotome probes is mechanical aspiration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 17 2009

Baylis Medical Company, Inc.
% Ms. Meghal Khakhar
Manager, Regulatory and Scientific Affairs
2645 Matheson Boulevard, East
Mississauga, Ontario
Canada L4W 5S4

Re: K092877
Trade/Device Name: InDiscal Aspiration Device and Accessories
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 9, 2009
Received: September 18, 2009

Dear Ms. Khakhar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

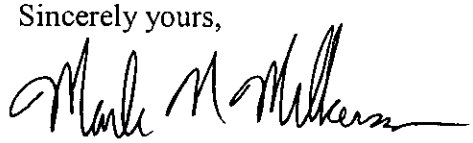
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092877

Device Name: InDiscal Aspiration Device and Accessories

Indications for Use:

The InDiscal Aspiration Device and Accessories are intended for aspiration of disc material during percutaneous discectomies in the lumbar, thoracic, and cervical regions of the spine.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092877